



Fast Track Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC60 -20-10 et seq.
Regulation title	Regulations Governing the Practice of Dentistry and Dental Hygiene
Action title	Monitoring requirement for nitrous oxide
Document preparation date	6/14/06

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The proposed action eliminates the requirement for a second person to be in the operatory with the dentist to monitor the patient during the administration of inhalation analgesia or nitrous oxide.

Statement of agency final action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On June 9, 2006, the Board of Dentistry took action to amend 18VAC60-20-10 et seq., Regulations Governing the Practice of Dentistry and Dental Hygiene, through the fast-track regulatory.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The Board has received numerous comments in writing and during board meetings from dentists who assert that the requirement for monitoring administration of inhalation analgesia (nitrous oxide) is overly burdensome and unnecessary for patient safety. Effective June 29 2005, the requirement to have a second person in the operatory with the patient to assist, monitor and observe the patient during the administration of nitrous was intended to provide an extra measure of patient safety and to protect the dentist from charges of improper conduct while the patient was under the influence of nitrous.

Subsequently, testimony to the Board has indicated that an additional person to monitor is not essential to ensure patient safety. Dentists contend that they have used nitrous safely for decades and that the additional monitoring is unnecessary. The dentist or hygienist performing a dental procedure would be observing the patient throughout that procedure, and once the administration of nitrous is discontinued, the patient can recover from its effects very quickly. Therefore, it may not be necessary to have close observation of the patient by a second person in the operatory. Many dentists do not employ an assistant who could serve that function, so the current regulation is burdensome to both the regulants and their patients. Several dentists have stated that the rule has caused them to quit offering their patients nitrous oxide; others may be continuing the practice without a second person to observe or using untrained office staff as monitors.

Without the availability of nitrous oxide, there are a number of people who will neglect their dental care or refuse to have a needed dental procedure. The Board believes the proposed change does not compromise the public health and safety in the administration of nitrous, but will enable and encourage more patients to seek dental care.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

As stated above, the Board has received numerous comments and complaints about the current regulation; there was unanimous support among board members for the change. If dental patients are being denied access to nitrous oxide in dental offices and are thereby avoiding routine or interventional treatments, it is necessary to revise the requirement as soon as possible.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The proposed action will eliminate the requirement for a second person to be in the operatory with the dentist to monitor the patient during the administration of inhalation analgesia or nitrous oxide.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
- 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
- 3) other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

There are no disadvantages to the public of this amendment. Consumers of dental services will be better protected by having access to inhalation analgesia in dental offices where there is not a second person available to monitor the patient during administration. Even in offices where such a person is available, the use for such a purpose potentially takes away time that such a person (hygienist or dental assistant) could be providing care or treatment for another patient. Consumers are also better served by having access to a full range of analgesia, provided it can be administered and monitored safely.

There are no disadvantages to the agency or the Commonwealth; a revised regulation should reduce the number of comments and potential violations of the rule

There are no other pertinent matters of interest.

Economic impact

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>The agency will incur some one-time costs (less than \$1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings. There are no ongoing expenditures related to this amendment. As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.</p>
<p>Projected cost of the regulation on localities</p>	<p>None</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the regulation</p>	<p>The individuals that may be affected by the regulation are dentists and their patients.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 5567 dentists licensed in Virginia, the majority of which would be considered small businesses.</p>
<p>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</p>	<p>The proposed change would have a positive impact on many practices in that regulations would no longer require a second person to monitor a patient receiving nitrous oxide during a dental procedure. If the dentist was required to employ a second person for that purpose, the cost could range from \$30,000 up, depending on the level of training for such person.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

There were no alternatives to an amendment to the requirement that would accomplish the purpose. The Board considered adoption of a guidance document, but such an interpretative document would not alter the language in the regulation or change the requirement.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods that will accomplish the objective which is to eliminate a barrier to dental care for patients that need inhalation analgesia to undergo a dental procedure. Failure to enact the proposed change would have an adverse impact on small businesses.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes.

Current section number	Current requirement	Proposed change and rationale
108	Establishes the requirements for the administration of anxiolysis or inhalation analgesia	An amendment in subsection C would eliminate the requirement for a second person to be in the operatory with the dentist to monitor the patient during the administration of inhalation analgesia or nitrous oxide. Another change would clarify that the dentist can either adjust the nitrous machine himself or request that a second person make an adjustment.